K102957

APR 2 8 2011

510(k) Summary

1. **Applicant**

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Matthews, NC 28104
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Application Correspondent:

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Date Prepared: October 1, 2010

2. **Device Name**

Common/Usual Name:	Intervertebral fusion device with bone graft, lumbar
Classification Name:	Intervertebral body fusion device
Regulation Number:	888.3080
Product Code:	MAX
Classification:	II
Panel:	Orthopedic

3. Predicate Devices

The Cutting Edge Spine Interbody Fusion Device (CES) is substantially equivalent to the following device:

510(k) Number	Device	Manufacturer
K090707	Talos Intervertebral Body Fusion Device	Meditech Advisors, LLC
P960025 (PMA)	Lumbar I/F Cage® System	DePuy Spine
P950002 (PMA)	BAK® Interbody Fusion System	Zimmer
K071724	Lucent device	Spinal Elements

4. Description of the Device

The CES device is a family of PEEK-OPTIMA spacers offered in a variety of widths and lengths. There are five main configurations: CES-PLIF, CES-LIF, CES-TLIF, CES-CLIF and CES-RLIF. The different configurations allow for multiple surgical technique options. The CES-PLIF, CES-LIF, CES-CLIF and CES-RLIF are generally rectangular in shape while the CES-TLIF is curved.

The CES implants are available in a range of sizes, as well as flat and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the spacers as an option to help allow for radiographic visualization. The hollow implants have holes through four sides for bone graft and an inserter instrument interface on the face. Teeth on top and bottom of the spacers improve fixation. The spacers themselves are made of biocompatible PEEK-Optima LT1 (per ASTM F2026-08) material and provided non-sterile for single-use.

5. Indications for Use

The Cutting Edge Spine Interbody Fusion Device (CES) is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The CES device is intended to be used with autologous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior, transforaminal, retroperitoneal or anterior approach. The CES-PLIF and CES-LIF are implanted in pairs, while the CES-TLIF, CES-CLIF and CES-RLIF devices may be implanted

singly or in pairs in the lumbosacral spine. The CES device is intended to be used with supplemental fixation.

6. Summary of Performance Data

The CES device was tested in compliance with FDA's guidance document titled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device". Preclinical testing according to ASTM F2077 and ASTM F2267, including static compression, static compression shear, static torsion, dynamic compression, subsidence and expulsion was conducted.

Preclinical testing demonstrated substantially equivalent performance characteristics to the identified predicate devices.

7. Safety & Effectiveness

The CES device is substantially equivalent to the identified predicate devices. All of these devices are made of biocompatible PEEK material, have similar shapes and sizes, have similar Indications for Use, are available by prescription only, and are provided non-sterile for single-use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cutting Edge Spine, LLC
% Mr. John Kapitan
Kapstone Medical, LLC
P.O. Box 1458
Waxhaw, North Carolina 28173

APR 2 8 2011

Re: K102957
Trade/Device Name: Cutting Edge Spine Interbody Fusion Devices (CES)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 15, 2011
Received: April 21, 2010

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102957

Indications for Use Statement

510(k) Number (if known): K102957

Device Name: Cutting Edge Spine Interbody Fusion Device (CES)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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